Listing of Supporting Declarations:

Exhibit	Name	Rule 132 Declaration	Curriculum Vitae
A	Claudia BOZZI, DDS	X	X
B	A.-J. CAMARDA, DDS	X	X
C	Eugene R. CASAGRANDE, DDS	X	X
D	Mark J. FRIEDMAN, DDS	X	Bio
E	Haruhisa FUKAYAMA, DDS, PhD, JBDA, IJBDA	X	X
F	Ralf E. GEBHARD, MD	X	X
G	Oscar GHELBER, MD	X	X
H	Adam S. LANDSMAN, DPM, PhD	X	X
I	Donald R. TANENBAUM, DDS, MPH	X	Brochure
J	Lance TIMMERMAN, DMD	X	None
K	Wayne P. WILLIAMS, BDS, MchD	X	X

Remarks/Arguments

Reconsideration of the subject application as amended hereinabove is respectfully requested.

The Examiner has rejected the pending claims on the following grounds:

A - They fail to comply with the written description requirement (35 USC §112);

B - They fail to comply with the enablement requirement (35 USC §112);

C - Some claims are anticipated by Brown (35 USC §102(e)); and

D - Some claims are obvious over Brown in view of Kuhle or Garnier (35 USC §103).

The Applicant respectfully traverses these rejections.

A. The Written Description Requirement

The Examiner takes the position that the specification fails to disclose: (1) a method of eliminating pain; (2) a method of eliminating pain-producing inflection; or (3) a method of preventing a needle from generating pain.

In response, the Applicant directs the Examiner's attention to the following passages in the specification as filed:

(i) (Page 1, Lines 7-10: Field of Invention) "More particularly, the invention pertains to a method for delivering an injection wherein the needle of the injection apparatus is simultaneously rotated and translated to reduce pain in the patient and to eliminate undesirable needle deflections."

(ii) (Page 23, Lines 3-6: Abstract) "The rotation of the needle insures that the needle is not deflected as it is advanced. In this manner, the amount of pain felt by the patient may be reduced, and the drug is delivered to accurately to the selected site."

(iii) (Page 8, Lines 8-11: Objectives and Summary of the Invention) "The present inventor has further discovered that needle deflection requires increased penetration force during the administration of an injection. It is believed that this increased penetration force results in increased and unnecessary tissue damage as well."

It should also be noted that the whole specification is devoted to needle deflection during injections in how to eliminate needle deflection. As discussed in the specification, and as evidenced by the attached declarations, it is well known in the art of anesthesiology that needle deflection has several undesirable effects. If a needle is deflected, the anesthetic is not delivered to the site or tissue region desired. It increases the required insertion force. It is obvious to a person skilled in the art that if a doctor applies more force to insert a needle, the patient's tissues are presenting more resistance to the needle advancement, and therefore the patient is feeling more pain. A further disadvantage of needle deflection is tissue damage that is also clearly associated with pain.

Additionally, if a needle is deflected and the anesthetic is not delivered to the site or tissue region desired, the injection is often ineffective because a reduced amount of anesthetic [numbing solution] at the desires site produces inadequate "numbing" (or anesthesia) effect thus resulting in increased pain. Hence, the elimination of needle deflection reduces pain of patients by allow greater accuracy of placement of medication at the intended site. Hence, in the present invention, pain reduction is implemented through reduced needle deflection, by the length of needle travel and duration, by reducing tissue tearing and by insuring that the anesthetic is accurately delivered to the desired site.

To summarize, the subject application explicitly addresses the fact that needle deflection causes pain. Moreover, this fact is well known in the art. The application further explicitly

discloses a technique for reducing or eliminating needle deflection. Therefore, it is respectfully submitted that claims directed to methods of reducing or eliminating pain by reducing needle deflection are clearly disclosed by the specification. The independent claims have been amended to recite in the preamble that pain reduction is implemented by reducing needle deflection.

B. The Enablement Requirement

The Examiner takes the position that the specification fails to provide a disclosure "to enable one skilled in the art to use the [claimed] method to provide painless needle deflection (or even reduce pain needle deflection) without undue experimentation. ... There is no description of the amount of deflection to avoid in order to prevent pain from any remaining deflection. ... The level of predictability in the art is very low because the subject matter is subjective pain in biological systems. Applicant has not provided any direction or working examples concerning the elimination of pain in advancing needles with reduced deflection. The quantity of experimentation would be large because of the biological variability and subjective nature of pain measurement. Because of these factors the examiner concludes that the method of eliminating pain, eliminating pain-reducing deflection, or preventing a needle from generating pain, as recited in the claims is not enabled."

As the Examiner correctly recognizes, pain management is highly subjective. The specification describes in detail the claimed procedure and provides some suggested parameters for the injections, including angles of rotation, speeds of insertion, whether the rotation should be in a single, or two directions, and so forth. Of course, the method claimed herein can be implemented manually–using a syringe, or with an automated injection device. If manual implementation is used, any parameters are merely guidelines since it would be impractical to require a doctor to rotate a syringe by an angle of, say 42.5 degrees! However,

contrary to the Examiner's assumptions, the exact parameters are not important. The Applicant has found that once the method is explained to skilled practitioner, the practitioner can readily implement it without the need for any accurate parameters.

In order to support this point, the Applicant hereby submits 11 declarations from various doctors. These doctors practice in various fields, including medicine dentistry, podiatry, and physical locations, including locations in the U.S., such as Long Island-NewYork, Chicago-Illinois, Houston-Texas, and Los Angeles-California as well as foreign countries, including Canada, United Kingdom, and Japan. Importantly, these doctors are eminent in their fields, having not only many years of practice, but also having published articles and lectured extensively. All these doctors have agreed with the following points:

(1) One problem in the field of dental or medical treatment and more particularly, during the injection of an anesthetic into a living tissue prior to performing clinical procedures pertains to needle bending. As a needle is introduced through tissues to a preselected site for delivering an anesthetic, it frequently bends. This action causes discomfort in the patient and pain. [1]In many instances, a patient either stiffens up, or, worse, tries to move involuntary away from the needle, or close his mouth, thereby causing even more discomfort.

(2) Initially, each doctor had some doubts that this procedure would work. However, he or she has tried this technique numerous times on patients and found that it is very effective in reducing needle bending and, subsequently, in reducing or eliminating patient discomfort and pain. Some of the doctors have tried out this technique hundreds of times.

(3) Each doctor found that the procedure was effective for as long as he or she kept the needle rotating to change the orientation of the bevel of the needle in somewhat

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[1]This point is also important with regard to the 35 USC 112 rejection discussed above.

continuous manner during the insertion, and that the total angle of rotation of the needle, or whether it was rotated only in a single direction, or back and forth, did not matter that much. Each doctor found that it was very easy to determine intuitively how much to rotate the needle from the reaction of the patient. More particularly, each doctor found that if he rotated the needle enough to prevent it from bending, the patient became uncomfortable as indicated by his body language and other indicia, including verbal communication from the patient, Because of this immediate voluntary or involuntary feedback from the patient, it was very easy to adjust the procedure to each patient as required.

In summary, it is respectfully submitted that contrary to the examiner's assertions, a person skilled in the art has no trouble practicing the claimed invention without any undue experimentation.

C. Anticipation by Brown

Some claims were rejected as being anticipated by Brown.

The present invention pertains to pain management during injections with a needle . As discussed in the specification, and other submitted materials, pain felt by patients during injections is a major problem in anaesthesiology. The present inventor has discovered that this pain can be reduced or prevented if, during the injection process, while the needle is advanced toward an injection site within a soft tissue, it is also rotated to eliminate deflections.

Brown discloses an injection syringe which is advanced into a predetermined position and then two drugs are released in sequence while the needle is turning about its axis thereby forming either a sphere, as seen in Figs. 2 and 3 or two joined spherical portions as seen in Fig. 4 (See also col. 1, lines 43-52). It is clear from the Brown specification and from the drawings that the needle is rotated only after it has reached the injection site. The claims clearly recite that in the present invention the needle is advanced and simultaneously rotated. In Brown, the

needle is clearly not simultaneously translated and rotated because the plume in Figs. 1-4 would have an elongated cylindrical shape and not a spherical shape. Moreover, Brown's Figures clearly illustrate that he was not aware of and did not appreciate the problems caused by needle deflection.

The Examiner has indicated that he is relying on Brown as teaching that it is well known to twist or turn a needle of a syringe while inserting it through tissue. Brown merely mentions that "the usual procedure is to insert the needle by a sharp jab or pushing action. Pressure is exerted to the plunger of the syringe to inject the contents. At times, a turning or twisting action may be employed to cause the needle to enter the tissue more easily or more easily affect removal." (col. 1, lines 16-22). This passage indicates that the rotation is performed either when the needle is to enter the tissue or when it is to be removed from the tissue. There is nothing in this passage to indicate that it is known in the prior art to rotate and translate the needle simultaneously.

The Examiner states in his most recent rejection that the Brown method "inherently eliminates pain during needle insertion because it makes the insertion easier with less tissue affected by the insertion." In response the independent claims have been amended to recite more clearly that injection is taking place, i.e., fluid is being inserted into the tissue while the needle is being advanced and rotated. This step is clearly not taught by Brown and, therefore, Brown does not anticipate the claims.

D. Obviousness

(1) The prior art does not disclose the present invention

Some claims were rejected as being obvious over Brown in view of Kuhle or Garnier. Kuhle discloses an injection needle having a very unique tip. The purpose of this tip is to

enable a clinician to insert a needle selectively along a curved path to avoid an obstruction. Thus, a person skilled in the art would not find this reference relevant since it has nothing to do with pain management. Kuhle does offer two methods of administering an injection which result in an overall straight or linear trajectory for a needle tip. One method (col. 7, lines 1-7) consists of rotating the needle by 360 degrees to thereby cause the deflection force on the needle tip to average out to zero. This suggests that the special tip described in the patent undergoes a curved path but when it has turned 360 degrees its final position is linear with its starting position. Nowhere does this mode of operation limit the needle deflection in between the starting and ending positions.

The second method (col. 7, lines 7-15) is to advance the needle tip in small incremental steps and at the end of each step to rotate the needle by 180 degrees. In this method, the tip moves radially back and forth in a zig-zag fashion. Again, there is no direction given by the reference on how to control the needle tip to control pain. Moreover, there is nothing in this reference to suggest to one skilled in the art how any of the issues raised in the patent have any relevance to injections.

The Examiner further rejected some of the claims as being obvious over Brown in view of Garnier. Garnier discloses a hand drill that uses a special needle as a drill bit to penetrate the bony tissues of a tooth root. Therefore, the needle is short, stubby, and thick and is not the kind of needle that is used in a syringe or other standard injection devices to deliver anesthetic into a soft tissue. Garnier states (at col 1,line 26) that:

> "*This object is achieved by providing the syringe with means for rotating the needle about its axis during the injection process"....*
> *"For this reason, it is preferred to cause the needle to oscillate in an angular sense about its axis, thereby avoiding injury or breakage if the needle bends following deflection".*

Garnier fails to describe pain management as it relates to movement of the needle. His only concern is to insure that the needle does not break. Moreover, just like Brown, Garnier teaches dispensing fluid only after the desired injection site has been reached. On the other hand, in the present invention, injection is taking place while the needle is advanced and rotated.

The above discussion covers the general concept of reducing or eliminating pain during an injection by applying a bidirectional motion to the injection needle. Another consideration for this concept is that, preferably, during this bidirectional motion, the needle should be advanced at a steady constant rate. As indicated in the specification and the claims (see claims 6 and 23), preferably this rate is in the range of 2-4mm/sec.

The Examiner has rejected claim 23 because, in his view, the rate of advancement is not important. The Applicant disagrees. Maintaining a uniform, consistent advancing rate (such as 2-4mm/sec) while simultaneously rotating is important to the method described, as it (1) ensures uniform movement of the needle through the tissue in a consistent manner, and (2) provides the reduction/elimination of pain (i.e., pain management) by minimizing/eliminating any inconsistent movements of needle known to cause stimulation to pain receptors in the body that do result in pain on insertion and movement of a needle. At the specified rate clearly directs the user not to use a high velocity (i.e., "jabbing technique") which can negate the benefits the method described.

The use of a consistent (uniform) advance rate (e.g., 2-4mm/sec) elimination/minimizes patient pain perception by providing the least amount of aberrant movement thereby eliminating/minimizing stimulation during movement of the needle this results in pain management from the gentle movement of the needle through tissue.

Kuhle makes no mention of the need or importance of advancing rate. Advancing rate is left to be arbitrary on could be done erratically or inconsisnt causing maximum stimulation of pain receptors producing an uncomfortable and painful experience for the patient.

Brown discusses that "At times, a turning or twisting action may be employed", (col 2, line 43) "rotating the needle of the syringe 360 degrees or while holding the needle stationary". Brown further teaches that *"jabbing is the usual procedure, but that turning or twisting may be employed at some time"* for the said reason of *"to get an easier entry"* . All these discussions of needle movement fail to discuss the importance or need for consistent (uniform) advance rate as described and claimed herein for pain management.

(2) Objective indicia of Unobviousness

The literature is repleat with studies, statistics and other analyses of the pain management aspects of injecting a patient. In fact, some studies have gone so far as to suggest that causing pain to patients during injection distresses health care providers and may be principal reason why some of these providers are resigning and leaving the field. These reports clearly point to the fact that pain management during injections to patient is a long felt and important field.

Despite the fact that there was this long felt need, there was an initial disbelief on the part of seasoned practitioners that the present invention would work. The declarations by well known authorities in the field amply illustrate and support this fact.

The long felt need for a solution to pain management and initial disbelief that the invention would work both support the conclusion that the claimed invention is unobvious.

In summary, the claims cover a method of controlling pain during injections that is not disclosed in any of the references. It is respectfully submitted that the subject application is now in condition for allowance.

Applicant hereby states that by the amendments made hereinabove, no new matter is being added to the subject application.

Consideration and entry into the record is respectfully requested.

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Respectfully submitted,

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